

OCT 1 2 2011

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1. Submitter's Information: 21 CFR 807.92(a)(1)

SAMSUNG MEDISON CO., LTD. 1003, Daechi-dong, Gangnam-gu, Seoul 135-280, Korea

Contact Person:

Kyeong-Mi, Park Regulatory Affairs Manager

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Data Prepared: July 11, 2011

2. Name of the device:

Common/Usual Name:

Diagnostic Ultrasound System and Accessories

Proprietary Name:

SONOACE R7 Diagnostic Ultrasound System

Classification Names:	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasound Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasound Transducer	892.1570	lTX

3. Identification of the predicate or legally marketed device:

K102065, SONOACE R7 Diagnostic Ultrasound System K093714, SONOACE X8 Diagnostic Ultrasound System

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4. Device Description:

The SONOACE R7 is a general purpose, mobile, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as B mode, M mode, Color Doppler imaging, Power Doppler imaging, PW/CW Spectral Doppler mode, Harmonic imaging, 3D imaging mode or as a combination of these modes. The SONOACE R7 also gives the operator the ability to measure anatomical structures and offers analysis packages that provide information that is used to make a diagnosis by competent health care professionals. The SONOACE R7 has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

The SONOACE R7 has been designed to meet the following product safety standards:

- UL 60601-1, Safety requirements for Medical Equipment
- CSA C22.2 No. 601.1, Safety requirements for Medical Equipment
- IEC60601-2-37, Diagnostic Ultrasound Safety Standards
- EN/IEC60601-1, Safety requirements for Medical Equipment
- EN/IEC60601-1-2, EMC requirements for Medical Equipment
- NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- IEC 61157, Declaration of the acoustic output
- ISO10993-1, Biocompatibility

5. Intended Uses:

The SONOACE R7 Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

The clinical applications include: Fetal, Abdominal, Pediatric, Small Organs, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Cardiac Adult, Cardiac Pediatric, Peripheral vessel.

6. Technological Characteristics:

The SONOACE R7 is substantially equivalent to the SONOACE R7 Diagnostic Ultrasound System, cleared via K102065, and the SONOACE X8 Diagnostic Ultrasound System, cleared via K093714. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All system allow for specialized measurements of structures and flow, and calculations.

END of 510(K) Summary



Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

OCT 1 2 2011

Samsung Medison Co., Ltd. % Mr. Mark Job Responsible Third Party Official Regulatory Technology Services LLC 1394 25th Street NW BUFFALO MN 55313

Re: K112646

Trade/Device Name: SONOACE R7 Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: September 9, 2011 Received: September 12, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SONOACE R7 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

<u>C2-8</u>	<u>HL5-12ED</u>	C4-9/10ED
ER4-9/10ED	<u>P2-4AH</u>	LN5-12
<u>EV4-9/10ED</u>	<u>3DC2-6</u>	P3-7AC
<u>L3-8</u>	3D4-8ET	3D4-9ES
<u>L5-12/50EP</u>	C2-5	**

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance: Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Jay Vaishnav at (301) 796-9580.

Sincerely Yours.

Mary S. Pastel, Sc.D.

Director

Division of Radiological Devices Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and Radiological Health

Enclosure(s)

510(k) Number (if known): <u>K11264</u>6

SECTION 1.3 INDICATIONS FOR USE

510(k) No.:

Device Name: SONOACE R7 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Ĭ			Mode of C	peration (*inc	ludes simultaneou	is B-mode)
General (Track Lonly)	Specific (Tracks [& III)	8	М	PWD	CMD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic	i						
	Fetal (See Note 3)	P	Р	[,		Р	Note I	Notes 2, 7, 8
	Abdominal	Р	P	Р	Р	ġ	Note I	Notes 2, 4, 7, 8
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)					ļ	Ĭ	
Fetal Imaging	Laparoscopic					i i	i	
& Other	Pediatric	P	Р	Р		P	Note 1	Note 2, 5, 6, 7, 8, 9
	Small Organ (See Note 5)	Ь	P	l,		9	Note 1	Note 2, 5, 6, 7, 9
	Neonatal Cephalic	N	N	7		N	Note I	Notes 2, 8
	Adult Cephalic	Р	Р	Ь	P	P	Note I	Note 4, 7
	Trans-rectal .	Р	Р	P		Р	Note 1	Note 2, 8
	Trans-vaginal .	Р	F'	Р		Р	Note 1	Note 2, 8
	Trans-urethral	1	i					
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	þ	Р		Р	Note 1	Note 2, 5, 6, 7, 9
	Musculo-skel. (Supertic.)	Р	Р	P		Р	Note I	Note 2, 5, 6, 7, 9
	Intra-luminal					İ	İ	
	Other (spec.)	1						
	Cardiac Adult	Р	Р	P	Р	Р	Note I	Note 4, 7
Cardiac	Cardiac Pediatric	P	Р	P	Р	Р	Note I	Note 4, 7
	Trans-esophageal (Cardiac)							·
	Other (spec.)	1					İ	
Peripheral	Peripheral vessel	Р	P	Р		Р	Note 1	Note 2, 5, 6, 7, 9
Vessel	Other (spec.)	1					i	···

N= new indication; P= previously cleared by FDA K102065; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M. B/PWD, B/Color Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OtVD)
Prescription Use (Per 21 CFR \$01.109)

(Division Sign-Off)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Indications for Use

510K 112646

510(k) No.:

Device Name: C2-8 for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	T			Mode of O	peration (*inch	ides simultaneous B	-mode)
General (Track Lonly)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic			<u> </u>				
	Fetal (See Note 3)	Р	P	Р		P	Note I	Notes 2, 7, 8
	Abdominal	P	Р	Ъ		₽	Note I	Notes 2, 7, 8
	Intra-operative (See Note 6)			i				
	Intra-operative (Neuro.)					-		······································
Fetal Imaging	Laparoscopic							
& Other	Pediatric	Р	Р	Р		P	Note I	Notes 2, 7, 8
	Small Organ (See Note 3)			i				
	Neonatal Cephalic	_						
	Adult Cephalic	_		i				
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)	_						
	Intra-luminal							
	Other (spec.)					•		
	Cardiae Adult							
Cardine	Cardiac Pediatric			İ				
	Trans-esophageal (Cardiac)	- -						····,
	Other (spec.)							
Peripheral	Peripheral vessel	1						
Vessel	Other (spec.)						-	

N= new indication; P= previously cleared by FDA K102065; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/Color Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 3: 3D imaging

Note 9: Panorunic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

Indications for Use

510(k) No.:

Device Name: ER4-9/10ED for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	[Mode of O	peration (*inclu	des simultaneous B-	mode)
General (Track Lonly)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppter*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal (See Note 3)							
	Abdominal							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)		_					
Fetal Imaging	Laparoscopic			İ				
& Other	Pediatric	ļ						
	Small Organ (See Note 5)							•••
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	Р	Р	P		Р	Note 1	Notes 2, 8
	Trans-vaginal	l,	Р	P		Р	Note I	Notes 2, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)			i				
	Musculo-skel. (Superfic.)			i				
	Intra-luminal				-			
	Other (spec.)		_					
	Cardiac Adult	1						
Cardiac	Cardiac Pediatric							
	Trans-esophageal (Cardiac)					-	-	
	Other (spec.)					·		
Peripheral	Peripheral vessel							
Vessel	Other (spec.)	1 1		-				

N= new indication; P= previously cleared by FDA K102065; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/Color Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices Office of In Vitro Diagnostic Device Evaluation and Safety

Indications for Use

510(k) No.:

Device Name: EV4-9/10ED for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application				Mode of O	peration (*inclu	des simultaneous B-	
General (Track Lonly)	Specific (Tracks I & III)	В	М	PWD	CMD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
· · · · · · · · · · · · · · · · · · ·	Fetal (See Note 3)							
	Abdominal							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
Fetal linaging	Laparoscopic			İ				
& Other	Pediatric							
	Small Organ (See Note 5)	_						
	Neonatal Cephalic							
	Adult Cephalic							
	Tituns-rectul	Р	Ь.	Р		Р	Note I	Notes 2, 8
	Trans-vaginal	Р	Р	l,		Р	Note I	Notes 2, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel, (Convent.)	1						
	Musculo-skel. (Supertie.)							
	Inua-luminal	1						
	Other (spec.)							
	Cardiac Adult							
Cardiae	Cardiac Pediatric					 -		
	Trans-esophageal (Cardiac)							
	Other (spec.)				•			
Peripheral	Peripheral vessel							
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA K102065; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/Color Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrottim and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Indications for Use

510K 1/1/2646

510(k) No.:

Device Name: L3-S for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application		Mode of Operation (* includes simultaneous B-mode)										
General (Track Lonly)	Specific (Tracks I & III)	В	М	ЬМD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)					
Ophthalmic	Ophthalmic												
···································	Fetal (See Note 3)												
	Abdominal												
	Intra-operative (See Note 6)												
	Intra-operative (Neuro.)	_											
Fetal imaging	Laparoscopie		i										
& Other	Pediatric	P	Р	Р		Р	Note 1	Note 2, 5, 6, 7, 9					
	Small Organ (See Note 5)	Р	l,	Р		Р	Note 1	Note 2, 5, 6, 7, 9					
	Neonatal Cephalic												
	Adult Cephalie	_	Ì	i									
	Trans-rectal												
	Trans-yaginal	_					i						
	Trans-urethral	\dashv						·····					
	Trans-esoph. (non-Cardiac)												
	Musculo-skel. (Convent.)	Р	P	P		Р	Note I	Note 2, 5, 6, 7, 9					
	Musculo-skel. (Superfic.)	Р	Ь	Р		P	Note I	Note 2, 5, 6, 7, 9					
	Intra-luminal						i						
	Other (spec.)												
	Cardiac Adult												
Cardiac	Cardiac Pediatric												
	Trans-esophageal (Cardiac)												
	Other (spec.)												
Peripheral	Peripheral vessel	Р	Р	Р		Р	Note I	Note 2, 5, 6, 7, 9					
Vessel	Other (spec.)												

N= new indication; P= previously cleared by FDA K102065; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/Color Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 3: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Per 21 CFR 801.109)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

Indications for Use

510K K112646

510(k) No.:

Device Name: L5-12/50EP for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	[des simultaneous E	
General (Track Lonly)	Specific (Tracks I & III)	В	М	PWD	CMD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal (See Note 3)							
	Abdominal							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric	L,	Р	P		þ	Note I	Note 2, 5, 6, 7, 9
	Small Organ (See Note 5)	P	Р	h		. P	Note I	Note 2, 5, 6, 7, 9
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	$\neg \vdash$						
	Trans-vaginal						Ī	
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Muscuło-skel. (Convent.)	Р	P	Р		Р	Note 1	Note 2, 5, 6, 7, 9
	Musculo-skel. (Superfic.)	P	Į,	P		Р	Note 1	Note 2, 5, 6, 7, 9
	Intra-luminal							
	Other (spec.)							
	Cardíae Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (Cardiac)			i				
	Other (spec.)			·				
Peripheral	Peripheral vessel	Р	Р	P		b	Note I	Note 2, 5, 6, 7, 9
Vessel	Other (spec.)			i i				

N= new indication; P= previously cleared by FDA K102065; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/Color Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of folliele development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) Prescription Use (Per 21 CFR \$01.109)

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) No.:

Device Name: HL5-12ED for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application						des simultaneous E	
General (Track Lonly)	Specific (Tracks (& III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic						_ [
 	Fetal (See Note 3)							
	Abdominal			l				
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)			ļ				
Fetal Imaging	Laparoscopic							
& Other	Pediatric	Р	P	P		Р	Note I	Note 2, 5, 6, 7, 9
	Small Organ (See Note 3)	Р	Р	P		Р	Note I	Note 2, 5, 6, 7, 9
	Neonatal Cephalic							
	Adult Cephalic	$\neg \vdash$						
	Trans-rectal							
•	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardine)						-	
	Musculo-skel. (Convent.)	Р	Р	Р		Р	Note I	Note 2, 5, 6, 7, 9
	Musculo-skel. (Superfic.)	Р	Р	Р		Ь	Note I	Note 2, 5, 6, 7, 9
	Intra-luminal			Ï				
	Other (spec.)							<u> </u>
	Cardiac Adult	1						Ţ.,
Cardiac	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral	Peripheral vessel	Р	P	Р		P	Note I	Note 2, 5, 6, 7, 9
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA K102065; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note I: B/M, B/PWD, B/Color Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Hannonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription Use (Per 21 CFR 801.109)

(División Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

Indications for Use

510K 1412646

510(k) No.:

Device Name: P2-4AH for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application						des simultaneous B-r	
General (Track Lonly)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal (See Note 3)							
	Abdominal	Р	P -	P	Р	р	Note I	Note 4, 7
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)			i				
Fetal Imaging	Laparoscopic							
& Other	Pediatric							
	Small Organ (See Note 5)	-						
[-	Neonatal Cephalic							
	Adult Cephalic	Р	Ь	Р	P	P	Note I	Note 4, 7
	Trans-rectal							
	Trans-vaginal			i				
	Trans-urethral							
	Trans-esoph. (non-Cardiae)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)	\top		-				
	Intra-luminal	<u> </u>	-					
	Other (spec.)	1						
	Cardiac Adult	P	Р	P	Р	Р	Note I	Note 4, 7
Cardiac	Cardiac Pediatric	P	P	Р	P	Р.	Note I	Note 4, 7
	Trans-esophageal (Cardiac)	\top		1				<u> </u>
	Other (spec.)	\top						
Peripheral	Peripheral vessel					<u> </u>		
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA K102065; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, BiColor Doppler, BiColor Doppler/PWD, BiPower Doppler/PWD, BiColor Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 3: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

Indications for Use

510(k) No.:

Device Name: 3DC2-6 for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	I	Mode of Operation (*includes simultaneous B-mode)									
General (Track Lonly)	Specific (Tmcks f & III)	В	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec)				
Ophthalmic	Ophthalmic											
	Fetal (See Note 3)	Р	P	Р		Р	Note I	Note 2, 7, 8				
	Abdominal	P	Þ	Р		Р	Note I	Note 2, 7, 8				
	Intra-operative (See Note 6)				-							
	Intra-operative (Neuro.)											
Fetal Imaging	Laparoscopic											
& Other	Pediatric	Р	6	Р	<u>-</u>	Р	Note I	Note 2, 7, 8				
	Small Organ (See Note 5)			i i		-						
	Neonatal Cephalic			i								
	Adult Cephalic						i					
	Trans-rectal											
	Trans-vaginal			i - i			İ					
	Trans-urethral											
	Trans-esoph. (non-Cardiae)											
	Museulo-skel. (Convent.)					***						
	Musculo-skel. (Supertic.)				i							
	Intra-teminal											
	Other (spec.)											
	Cardiae Adult							·				
Cardiac	Cardiac Pediatric											
	Trans-esophageal (Cardiac)											
	Other (spec.)	1										
Peripheral	Peripheral vessel											
Vessel	Other (spec.)											

N= new indication; P= previously cleared by FDA K102065; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note I: B/M, B/PWD, B/Color Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, serotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K 112646

Indications for Use

510(k) No.:

Device Name: 3D4-8ET for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application			Mode of Operation (*includes simultaneous B-mode)								
General (Track Lonly)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)				
Ophthalmic	Ophthalmic											
	Fetal (See Note 3)	Р	Р	Р		Р	Note I	Note 2, 7, 8				
	Abdominal	Р	Р	P		Р	Note I	Note 2, 7, 8				
	Intra-operative (See Note 6)											
	Intra-operative (Neuro.)											
Fetal Imaging	Laparoscopic											
& Other	Pediatric	Р	Ь	5		P	Note I	Note 2, 7, 8				
	Small Organ (See Note 5)					-						
	Neonatal Cephalic											
	Adult Cephalic											
	Trans-rectal											
	Trans-vaginal											
	Trans-urethral	1		i								
	Trans-esoph. (non-Cardiac)											
	Musculo-skel. (Convent.)											
	Musculo-skel. (Superfic.)											
	Intra-luminal			i								
	Other (spec.)			İ								
	Cardiae Adult											
Cardiac	Cardiac Pediatric						<u>-</u>					
	Trans-esophageal (Cardiac)											
	Other (spec.)											
Peripheral	Peripheral vessel	1										
Vessel	Other (spec.)	-1					-					

N= new indication; P= previously cleared by FDA K102065; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, BiColor Doppler, B/Color Doppler/PWD, BiPower Doppler/PWD, BiColor Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes intertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Salety

510(k) No.:

Device Name: C2-5 for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

•	Clinical Application				Mode of Operation (*includes simultaneous B-mode)									
General (Track Lonly)	Specific (Tracks I & [II])	В	M	DWG	CMD	Color Doppler*	Combined* (Spec.)	Other (Spec.)						
Ophthalmic	Ophthalmic													
	Fetal (See Note 3)	N	И	И		И	Note 1	Notes 2, 7, 8						
	Abdominal	Ŋ	И	И		N	Note 1	Notes 2, 7, 3						
	Intra-operative (Sec Note 6)													
	Intra-operative (Neuro.)							· · · · · · · · · · · · · · · · · · ·						
Fetal Imaging	Laparoscopic													
& Other	Pediatric	N	N	N		N	Note I	Notes 2, 7, 8						
	Small Organ (See Note 5)													
	Neonatal Cephalic			i										
	Adult Cephalic			i i	i									
	Trans-rectal													
	Trans-vaginal	1		i										
	Trans-urethral			i										
	Trans-esoph. (non-Cardiae)			İ	i		i	 ·						
	Musculo-skel. (Convent.)													
	Musculo-skel. (Superfic.)			i										
	Intra-luminal			i										
	Other (spec.)						<u> </u>							
	Cardiac Adult			 		,	Ī							
Cardiac	Cardiac Pediatric			i			j							
	Trans-esophageal (Cardiae)			i			i i							
	Other (spec.)						i							
Peripheral	Peripheral vessel						· · · · · · · · · · · · · · · · · · ·							
Vessel	Other (spec.)				j									

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/Color Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K /12646

510(k) No.:

Device Name: C4-9/10ED for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation (*includes simultaneous B-mode)								
General (Track Lonly)	Specific (Tracks 1 & III)	В	М	PWD	CMD	Color Doppler*	Combined ^s (Spec.)	Other (Spec.)	
Ophthalmic	Ophthalmic								
•	Feral (See Note 3)	Р	Р	Р		P	Note I	Notes 2, 8	
•	Abdominal	Р	Р	P		P	Note I	Notes 2, 8	
	Intra-operative (See Note 6)								
	Intra-operative (Neuro.)							•	
Fetal Imaging	Laparoscopic			ĺ					
& Other	Pediatric	Р	f,	Р		P	Note I	Notes 2, 8	
	Small Organ (See Note 5)	P	þ	P		Р	Note I	Notes 2, 3	
	Neonatal Cephalic	. [5	Р	Ь		P	Note	Notes 2, 8	
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral			[
	Trans-esoph. (non-Cardiac)	1		i	-				
	Musculo-skel. (Convent.)	T i							
	Musculo-skel. (Superfic.)								
	lnira-luminal								
	Other (spec.)				i				
	Cardiac Adult			İ				•	
Cardiac	Cardiae Pediatrie								
	Trans-esophageal (Cardiac)	1							
	Other (spec.)				j				
Peripheral	Peripheral vessel	l,	l,	Р		ļ,	Note I	Notes 2, 8	
Vessel	Other (spec.)					-			

N= new indication; P= previously cleared by FDA K093714; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/Color Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8, 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety .

h110646

510(k) No.:

Device Name: LN5-12 for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation (*includes simultaneous B-mode)								
General (Track Lonly)	Specific (Tracks I & III)	В	М	PWD	CMD	Color Doppler*	Combined* (Spec.)	Other (Spec.)			
Ophthalmic	Ophthalmic										
	Fetal (See Note 3)										
	Abdominal										
	Intra-operative (See Note 6)										
	Intra-operative (Neuro.)										
Fetal Imaging	Laparoscopic										
& Other	Pediatric	P	р	Р		þ	Note I	Notes 2,5,6			
	Small Organ (See Note 5)	Ъ	Р	P		Р	Note 1	Notes 2,5,6			
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal			i i							
	Trans-urethral										
	Trans-esoph. (non-Cardiac)	_									
	Musculo-skel, (Convent.)	P	P	Р		Р	Note I	Notes 2,5,6			
	Musculo-skel. (Superfic.)	P	₽	Р		р	Note I	Notes 2,5,6			
	Intra-luminal			İ				- · ·			
	Other (spec.)										
	Cardiac Adult	1						_			
Cardiac	Cardiac Pediatric		_								
	Trans-esophageai (Cardiac)										
	Other (spec.)			i i							
Peripheral	Peripheral vessel	Р	P	Р		Р	Note 1	Notes 5,6			
Vessel	Other (spec.)										

N= new indication; P= previously cleared by FDA K103722; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/Color Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note \$: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

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510(k) No.:

Device Name: P3-7AC for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application				Mode of Operation (*includes simultaneous B-mode)									
General (Track Lonly)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)						
Ophthalmic	Ophthalmic				Ì									
	Fetal (See Note 3)	1												
	Abdominal	Р	ין	12	þ	L,	Note I	Note 4, 7						
	Intra-operative (See Note 6)				ĺ									
	Intra-operative (Neuro.)			i										
Fetal Imaging	Laparoscopic						1							
& Other	Pediatric													
	Small Organ (See Note 5)			i										
	Neonatal Cephalic			İ										
	Adult Cephalic	P	l,	Р	['	P	Note I	Note 4, 7						
	Trans-rectal	_			İ									
	Trans-vaginal	_		İ		· · · · · · · · · · · · · · · · · · ·		71-1-370170-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-						
	Trans-urethral			ĺ	j									
	Trans-esoph. (non-Cardiac)													
	Musculo-skel. (Convent.)							·						
	Musculo-skel. (Supertic.)			 i	1									
	Intra-luminal													
	Other (spec.)			İ	i									
	Cardiac Adult	P	(1	Р	Р	P	Note I	Note 4, 7						
Cardiac	Cardiac Pediatric	l,	Р	Р	Р	Р	Note I	Note 4, 7						
	Trans-esophageal (Cardiac)													
	Other (spec.)				_	-								
Peripheral	Peripheral vessel													
Vessel	Other (spec.)					-								

N= new indication; P= previously cleared by FDA K093714; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

- Note 1: B/M, B/PWD, B/Color Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD, B/Color Doppler/Color M
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

Indications for Use

510K 1/2 1/2 Ce4 Ce

510(k) No.:

Device Name: 3D4-9ES for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation (*includes simultaneous B-mode)									
General (Track Lonly)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)		
Ophthalime	Ophthalmic									
	Foul (See Note 3)									
	Abdominal									
	Intra-operative (See Note 6)									
	Intra-operative (Neuro.)									
Fetal Imaging	Laparoscopic									
& Other	Pediatric			İ						
	Small Organ (See Mote 5)			<u>i</u>						
	Neonatal Cephalic							,		
	Adult Cephalie					· · · · · · · · · · · · · · · · · · ·				
	Trans-rectal	Р	Р	Ъ		P	Note I	Note 2, 7, 8		
	Frans-vaginal	Р	P	Ρ		Р	Note I	Note 2, 7, 8		
	Trans-urethral			i						
	Trans-esoph. (non-Cardiac)									
	Musculo-skel. (Convent.)									
	Musculo-skel, (Superfie.)					,				
	Intra-luminal									
	Other (spec.)									
	Cardiac Adult									
Cardiac	Cardiae Pediatrie			i						
	Trans-esophageal (Cardiac)									
	Other (spec.)									
Peripheral	Peripheral vessel							··· · · · · · · · · · · · · · · · · ·		
Vessel	Other (spec.)									

N= new indication: P= previously cleared by FDA K093714; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/Color Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OFVD)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

Indications for Use

510K H112646